CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 31.11
TITLE: SMALL INTESTINE (SI) COMBINED SMALL INTESTINE-LIVER (SI/L), AND MULTIVISCERAL TRANSPLANTATION

AUTHORITY: 38 USC 1713; 38 CFR 17.270(a) and 17.272(a)

RELATED AUTHORITY: 32 CFR 199.4(e)(5)

TRICARE POLICY MANUAL: Chapter 3, Section 1.6D

I. EFFECTIVE DATE

A. January 1, 1996, for small intestine and combined small intestine-liver transplants.

B. February 1, 1998, for multivisceral transplants.

II. POLICY

A. Preauthorized benefits are allowed for small intestine (SI) and small intestine-liver (SI/L) transplantation and multivisceral transplantation using the criteria contained within this policy.

B. Small Intestine Transplantation. Medically necessary services and supplies related to SI transplantation may be cost shared when the transplant is performed at a Medicare, TRICARE or VA approved transplant center, for pediatric patients under the age of 16 who:

1. are suffering from irreversible intestinal failure, either functional or anatomic, requiring long term parental nutrition,

2. have tried and considered all other medically appropriate medical and surgical therapies that might have been expected to yield both short and long-term survival comparable to that of transplantation,

3. have a parent or legal guardian who has a realistic understanding of the range of clinical outcomes that may be encountered, and

4. plans for long-term adherence to a disciplined medical regimen that is feasible and realistic.

C. Small Intestine-Liver Transplantation. Medically necessary services and supplies related to combined SI/L transplantation may be cost shared when the transplant is performed at a Medicare, TRICARE or VA approved transplant center, for pediatric and adult patients who:

1. have presence of end-stage parental nutrition induced liver disease, and

2. meet the above patient selection criteria for SI transplantation and the patient selection criteria for liver transplantation (see Chapter 2, Section 31.7, *Liver Transplantation*).

Note: Small intestine-transplantation-alone is restricted to pediatric patients under the age of 16. Combined small-intestine/liver transplantation is covered for pediatric and adult patients who meet patient selection criteria.

D. Multivisceral Transplantation. Medically necessary services and supplies related to multivisceral transplantation may be cost shared when the transplantation is performed at an approved Medicare, TRICARE or VA transplantation center for pediatric and adult patients who meet all of the following criteria.

1. Patients must have short bowel syndrome with evidence of severe liver dysfunction and/or have other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis, and the superior mesenteric artery or pseudo-obstruction affecting the entire gastrointestinal tract.

2. Patients must have tried or considered all other medically appropriate medical and surgical therapies that might have been expected to yield both short and long-term survival comparable to that of transplantation.

3. Pediatric patients should have a parent or legal guardian who has a realistic understanding of the range of clinical outcomes that may be encountered. Adult patients should also have a realistic understanding of the range of clinical outcomes that may be encountered.

4. Patients must have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.

E. Donor selection criteria:

1. for SI transplantation, cytomegalovirus (CMV) seropositive negative donors shall be used, and

2. for combined SI/L transplantation, CMV seropositive donors will be allowed secondary to CMV seropositive negative donors if there is a shortage of organs available.

F. For a preauthorized patient, cost sharing of medically necessary services and supplies related to SI, combined SI/L, and multivisceral transplantation for:

1. evaluation of a potential candidate's suitability for SI, combined SI/L or multivisceral transplantation whether or not the patient is ultimately accepted as a candidate for transplantation,

2. pre and post-transplant inpatient hospital and outpatient services,

3. surgical services and pre and post-operative services of the transplant team,

4. the donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center,

5. the maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met,

6. donor costs,

7. blood and blood products,

8. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and generally accepted practice within the general medical community (i.e., proven),

9. complications of the transplant procedure, including inpatient care, management of infection and rejection episodes,

10. periodic evaluation and assessment of the successfully transplanted patient,

11. hepatitis B and pneumococcal vaccinations for patients undergoing transplantation,

12. DNA-HLA tissue typing in determining histocompatibility, and

13. transportation of the patient by air ambulance and the services of a certified life support attendant.

G. Benefits are allowed for hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

H. Benefits may be allowed for DNA-HLA tissue typing in determining histocompatibility.

III. POLICY CONSIDERATIONS

A. Preauthorization and retrospective authorization of SI, combined SI/L or multivisceral transplantation must meet the following two requirements:

1. patient meets (or as of the date of transplantation would have met) patient selection criteria, and

2. transplant facility is (or as of the date of transplantation would have been) Medicare, TRICARE, or VA approved for SI and/or combined SI/L transplantation at the time of transplantation.

B. In those cases where the beneficiary fails to obtain preauthorization, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization.

C. Effective for admissions on or after October 1, 2001, SI, SI/L, and multvisceral transplantations shall be reimbursed under the assigned DRG based on the patient's diagnosis. Claims for admissions prior to October 1, 2001, shall be reimbursed based on billed charges.

D. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost shared on an inpatient basis. Scheduled or chartered transportation may be cost shared.

E. Benefits will be allowed for donor costs (see Chapter 2, Section 31.1, *Donor Costs).*

F. Charges made by the donor hospital will be cost shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the beneficiary (see Chapter 2, Section 31.1, *Donor Costs*).

G. Acquisition and donor costs are not considered to be components of the services covered under the DRG and will be reimbursed based on billed charges. These costs must be billed separately on a standard UB-92 claim form in the name of the beneficiary (see Chapter 2, Section 31.1, *Donor Costs*).

H. Transportation of the patient by air ambulance may be cost shared when determined to be medically necessary (see Chapter 2, Section 32.1, *Ambulance Service).*

I. When a preauthorized candidate is discharged less than 24-hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

IV. EXCLUSIONS

A. Administration of an experimental or investigational (unproven) immunosuppressant drug that is not FDA approved or has not received CHAMPVA approval as an appropriate "off label" drug indication (see Chapter 2, Section 30.8, *Immunosuppression Therapy*, for specific requirements).

B. All services and supplies which can be provided through research funds available for all or part of the cost of transplantation. Research funds which require a financial resources test (means test) to qualify for such funds shall not be considered available to the beneficiary.

C. Services, supplies, or devices, even those used in lieu of the transplantation, when determined to be related or integral to an experimental or investigational (unproven) procedure, may not be cost shared (see Chapter 2, Section 16.5, *Experimental/Investigational (Unproven) Procedures*).

D. Services and supplies provided at no cost to the beneficiary (or sponsor) who has no legal obligation to pay. This includes expenses or charges that are waived by the transplantation center.

E. Pre or post-transplant non-medical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members).

F. SI transplantation is excluded when the following contraindications exist:

1. significant cardiopulmonary insufficiency,
2. history of presence of aggressive and/or incurable malignancy,
3. persistent abdominal or systemic infection,
4. severe autoimmune disease,
5. severe immunodeficiency disease, and
6. significant alcohol and/or drug abuse.

G. Combined SI/L transplantation is excluded when:

1. any of the above contraindications for SI transplantation exist, and/or
2. any of the contraindications for liver transplantation (see Chapter 2, Section 31.7, *Liver Transplantation*) exist.

H. Transportation of an organ donor.

END OF POLICY